Decision Memo for Magnetic Resonance Angiography of the Abdomen and Pelvis (CAG-00142N)

Decision Summary

CMS intends to issue a positive national coverage determination expanding coverage of MRA to include imaging the renal arteries and the aortoiliac arteries in the absence of abdominal aortic aneurysm or aortic dissection. MRA should be obtained in those circumstances in which using MRA is expected to avoid obtaining contrast angiography (CA), when physician history, physical examination and standard assessment tools provide insufficient information for patient management, and obtaining an MRA has a high probability of positively affecting patient management. However, CA may be ordered after obtaining the results of an MRA in those rare instances where medical necessity is demonstrated. Medicare contractors should establish criteria for demonstrating medical necessity.

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Decision Memo

This decision memorandum does not constitute a national coverage determination (NCD). It states CMS's intent to issue an NCD. Prior to any new or modified policy taking effect, CMS must first issue a manual instruction giving specific directions to our claims-processing contractors. That manual issuance, which includes an effective date, is the NCD. If appropriate, the Agency must also change billing and claims processing systems and issue related instructions to allow for payment. The NCD will be published in the Medicare Coverage Issues Manual. Policy changes become effective as of the date listed in the transmittal that announces the Coverage Issues Manual revision.

To: Administrative File: CAG-00142N
Reconsideration of Coverage Issues Manual Section 50-14: Magnetic Resonance Angiography of the Abdomen and Pelvis

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Subject: Decision Memorandum for Reconsideration of Coverage Issues Manual Section 50 -14: Magnetic Resonance Angiography of the Abdomen and Pelvis

Date: April 15, 2003

This memorandum serves five purposes: (1) describes magnetic resonance angiography; (2) reviews the history of Medicare's coverage of magnetic resonance angiography in the diagnosis of circulatory disorders and provides a timeline of recent activities; (3) analyzes and presents relevant scientific and clinical literature on the use of magnetic resonance angiography, and its impact as a diagnostic device on patient management for patients with circulatory disorders; and (4) delineates the reasons for issuing a positive national coverage determination to expand coverage for magnetic resonance angiography of the renal and aortoiliac arteries separate from abdominal aortic aneurysm or aortic dissection when used to avoid obtaining a contrast angiography study.

I. Clinical Background

Magnetic resonance angiography (MRA) is a non-invasive diagnostic test that is an application of magnetic resonance imaging (MRI). By analyzing the amount of energy released from tissues exposed to a strong magnetic field, MRA provides images of normal and diseased blood vessels as well as visualization and quantification of blood flow through these vessels.

Phase contrast (PC) and time-of-flight (TOF) are the currently available MRA techniques. PC measures the difference between the phases of proton spins in tissue and blood, and measures both the venous and arterial blood flow at any point in the cardiac cycle. TOF measures the difference between the amount of magnetization of tissue and blood, and provides information on the structure of blood vessels, thus, indirectly measuring blood flow. Two-dimensional (2D) and three-dimensional (3D) images can be obtained using each method.

Contrast-enhanced MRA (CE-MRA) involves blood flow imaging after the patient receives an intravenous injection of a contrast agent. Gadolinium, a non-ionic element, is currently used as a magnetic resonance contrast agent. Gadolinium affects the way in which tissues respond to magnetization, resulting in better visualization of structures when compared to unenhanced studies. Unlike ionic (i.e., iodine-based) contrast agents used in contrast angiography (CA), allergic reactions to gadolinium are extremely rare. Additionally, gadolinium does not cause the kidney failure occasionally seen with ionic contrast agents. Physicians elect to use a specific MRA or CA technique based upon a patient's clinical situation.

Currently CMS covers the use of MRA in imaging the renal and aortoiliac arteries only in the presence of abdominal aortic aneurysm or aortic dissection and this current decision memorandum investigates the use of MRA in renal and aortoiliac arteries separate from these two aforementioned clinical conditions. While not exhaustive, the list of clinical conditions addressed by the current memorandum includes MRA's use in imaging patients with secondary hypertension to diagnose renal artery stenosis, to evaluate for occlusion of the aortic bifurcation (e.g., Leriche Syndrome), and to evaluate the proximal vessels as part of the work-up for patients with peripheral vascular disease. Regardless of the indication for which MRA is ordered, MRA, like any diagnostic imaging modality, is ordinarily preceded by a complete physical work-up, including any appropriate laboratory tests, and should be undertaken with a high degree of clinical suspicion. Inherent in this discussion of MRA's use in these clinical conditions is that physicians have followed accepted clinical, evidence-based, practices, and have turned to diagnostic imaging only after other, more standard investigations have been inconclusive.

In this decision memorandum, contrast angiography and digital subtraction angiography (DSA) are discussed as reference standards against which MRA is compared. CA and DSA are similar techniques and can be considered interchangeably in the discussion herein.

II. History of Medicare's Coverage of MRA and Timeline of Recent Activities

Current Coverage Issues Manual (CIM) Policy: Medicare currently has a national coverage determination concerning MRA, which is listed in Section 50-14 of the Coverage Issues Manual. The current policy provides coverage for certain indications but excludes other uses of MRA to image blood vessels in the abdomen and pelvis. On July 1, 2002 Medicare formally accepted a request for reconsideration from The American College of Radiology, The Society of Cardiovascular & Interventional Radiology, The American College of Cardiology, and The Society for Vascular Medicine and Biology to amend the existing NCD to expand coverage for CE-MRA of the abdomen and pelvis to include:

1. Renal arteries separate from abdominal aortic aneurysm (AAA) or aortic dissection;
2. Aortoiliac arteries separate from abdominal aortic aneurysm (AAA) or aortic dissection; and
3. Contrast angiography (CA) as an adjunct service to CE-MRA when clinically warranted.

Benefit Category Determination: CMS has determined that MRA is a diagnostic test and falls under section 1861(s)(3) of the Social Security Act (hereafter referred to as the "Act") (outpatient diagnostic services), section 1861(b)(3) of the Act (inpatient diagnostic services), and section 1861(s)(1) of the Act (physician services).

Timeline of Recent Activities:

July 1, 2002	Formal request for reconsideration letter accepted by CMS.
July 23, 2002	Additional time needed to complete the review. Due date will be extended to November 15, 2002.

III. FDA Status

The Food and Drug Administration (FDA) originally approved MRA imaging devices under a March 1988 pre-market approval (PMA) supplement for a 0.5 Tesla Picker MRI device with motion artifact suppression technology (MAST) software. These devices are approved for visualization of blood flow.

IV. General Principles for the Evaluation of Diagnostic Tests

When CMS reviews a diagnostic test for a national coverage determination, among other things, it evaluates whether the test is reasonable and necessary. CMS considers, in part, the accuracy and impact of the test on patient management. (42 C.F.R. § 410.32.)

An important consideration in reviewing whether a diagnostic test is reasonable and necessary is its validity (sensitivity and specificity) and reliability (inter-observer reliability) when compared to an existing diagnostic test (reference test) used for the same purpose. Sensitivity refers to the ability of a test to correctly identify patients who have the disease as identified by the reference test. In the case of MRA for detection of arterial stenosis of the abdomen and pelvis, low sensitivity means that the results of the MRA will lead to conclusions that stenosis exists in arteries that are, in fact, not stenotic. This could lead to unneeded intervention. Specificity refers to the ability of a test to correctly identify patients who do not have the disease. Following from this, if MRA had a low specificity in detecting stenotic arteries in the abdomen and pelvis it would miss stenotic arteries in need of possible intervention. It is important to keep in mind that the validity of a diagnostic test is relative to the best available reference test and the pre-test probability of having the disease. Diagnostic test validity also depends on when, in the course of disease management, the test is conducted. However, even if the information provided by the test is accurate but it does not alter patient management, CMS may determine the test is not reasonable and necessary for a given condition.

When reviewing studies that investigate a diagnostic modality, important aspects of the study design include, but are not limited to, the following:

1. The study uses a credible reference standard;
2. The reference standard is independently interpreted from the diagnostic test of interest, and the observers have no knowledge of the results of the other test;
3. Patients are selected with as little bias as possible;
4. When possible, an analysis of inter-observer reliability is conducted for both the reference and the diagnostic test under consideration; and,
5. The analysis addresses variables that may affect test results.
6. In addition, when making national coverage determinations, CMS considers other forms of medical, technical, and scientific evidence including clinical experience.

V. Summary of Evidence

In the current body of literature, the reference standard against which MRA is compared is contrast angiography (CA). CA is an accepted imaging modality used to image renal and pelvic vessels. It is also recognized by CMS that information obtained on CA positively affects patient management decisions. As such, in reviewing the MRA literature, the important issue is whether MRA provides equally or more accurate diagnostic information than CA. If this question can be answered affirmatively, CMS can also conclude that MRA would have a positive effect on patient management decisions.

Selection of Articles

The evidence reviewed was culled from: (1) articles submitted by the requestors; (2) an existing technology assessment; and, (3) a literature search of the PubMed database. The requestors submitted a list of 48 articles to support their request for coverage of MRA of the abdomen and pelvis. The bibliographies of each of these references were reviewed to identify additional relevant articles. CMS also reviewed a technology assessment (TA) published in April 1997 by the National Blue Cross and Blue Shield Association's Technology Evaluation Center (TEC) entitled "Magnetic Resonance Angiography of the Abdomen." CMS also performed a literature search in PubMed, a database maintained by the National Library of Medicine. The search encompassed articles inclusive of 1998 through 2002. CMS did not search for articles published prior to 1998 because the TEC assessment for Blue Cross and Blue Shield included an exhaustive literature review through 1997.

The limits of our PubMed search excluded non-English articles, studies with fewer than 10 cases, and those not involving human subjects. The search terms used were:

- Angiography, comparative studies
- Magnetic resonance angiography, vascular studies
- Magnetic resonance angiography, abdomen
- Magnetic resonance angiography, pelvis
- Magnetic resonance angiography, contrast angiography
- Magnetic resonance angiography, renal artery
- Renal angiography
- Gadolinium-enhanced Magnetic Resonance Angiography
- Contrast-enhanced Magnetic Resonance Angiography

From the initial PubMed yield, CMS then excluded abstracts, case reports, review articles, meta-analyses, cost-effectiveness studies, studies of stenoses that were not hemodynamically significant (defined in the following paragraph), studies lacking a reference standard, and those lacking sufficiently detailed information on study design or discussion of results. Using these search terms and exceptions, CMS identified 11 articles in addition to those submitted by the requestors. Of the 48 articles submitted by the requestors, 13 met the above criteria yielding a total of 24 articles reviewed for this memorandum. A summary of these 24 articles is provided in Table 1.

The literature consistently identified 50% stenosis as the threshold for clinically significant flow restrictive disease. Thus, for purposes of this review, hemodynamically significant arterial stenosis was defined as >50% and this threshold is used throughout this decision memorandum.

In addition, CMS received public comments in support of MRA for the indications submitted by the requestors. Harris Methodist Fort Worth Hospital submitted 23 abstracts along with their letter of support. A letter of support from the Florida Radiological Society, Inc. included five full-text articles. CMS applied the same inclusion/exclusion criteria listed above to these additional submitted pieces of information. None of the aforementioned material submitted by the public met CMS inclusion/exclusion criteria, and, while considered in CMS's decision-making process, were weighed proportionate to their scientific strength. Finally, CMS received supporting public comment from the Renal Physicians Association and the Medical Imaging Contrast Agent Association, although without supporting literature. CMS addresses the issues raised in these letters in the CMS Analysis section below.

A. MRA imaging of renal arteries separate from abdominal aortic aneurysm (AAA) or aortic dissection

CMS reviewed 14 articles: Bongers et al (2000), Chan et al (2001), De Cobelli et al (1996), De Cobelli et al (2000), De Haan et al (1996), Fain et al (2001), Hahn et al (1999), Huber et al (2001), Korst et al (2000), Mittal et al (2001), Qanadli et al (2001), Thorton et al (1999), Voiculescu et al (2001), and Volk et al (2000). These studies investigated the use of CE-MRA in imaging the renal arteries outside of an associated AAA or aortic dissection (indications for imaging for which CMS already provides coverage). A summary of these 14 articles follows.

Bongers et al (2000) prospectively studied 43 consecutive patients with suspected renal artery stenosis (RAS) using captopril renography, CE-MRA, and digital subtraction angiography (DSA). Separate radiologists and nuclear medicine physicians read the different image studies in a masked fashion. CE-MRA and captopril renography were compared to DSA and not to each other. When comparing the CE-MRA to DSA, CE-MRA yielded a sensitivity and specificity of 100% and 94% respectively.

Out of a pool of 196 kidney transplant recipients, Chan et al (2001) prospectively studied 17 patients having a systolic bruit in the region of their transplant. The study compared 3D CE-MRA to DSA for one artery in each patient. All DSAs were conducted within five weeks of CE-MRA. A single radiologist independently compared DSA findings to CE-MRA, although it is uncertain whether the assessor was masked to the initial DSA results. When compared to DSA, CE-MRA was 100% sensitive in the iliac artery, graft renal artery, and at the artery anastomosis. CE-MRA specificity was 100% for the iliac artery, 100% for the graft renal artery, and 83% at the artery anastomosis. The authors report 2 false positives (FP), one of these resulting from turbulence in a sharply kinked transplanted artery.

De Cobelli et al (1996) prospectively studied 50 consecutive patients with suspected renocardiovascular disease. Of these 50 patients, 28 had a confirmatory contrast angiography (CA) examination as the reference standard. No explanation was given as to why 22 of the 50 patients did not receive a CA. CE-MRAs were analyzed in consensus by two radiologists who where masked to the CA findings. When compared with CA, CE-MRA's sensitivity and specificity was 90% and 99% respectively.

De Cobelli et al (2000) prospectively studied 45 patients with suspected RAS. Of these, the first 32 patients initially underwent unenhanced MRA to help ensure accurate placement of contrast volume for the CE-MRA conducted immediately thereafter. The remaining 13 had CE -MRA without an initial unenhanced MRA. The MRA results reported in this study, however, were for the 45 combined CE-MRA procedures. All patients also underwent color Doppler ultrasonography prior to undergoing DSA. One vascular radiologist, who was masked to the MRA results, read the DSA images while two radiologists, in consensus and masked to the DSA results, graded the MRA findings. An additional, masked radiologist read ultrasound studies. When compared with DSA, CE-MRA sensitivity was 100%, and specificity was 93%. Ultrasound sensitivity and specificity were 79% and 93% respectively. For totally occluded vessels, sensitivity and specificity were separately reported at 100%. Additionally, CE-MRA depicted 102 of 103 arteries seen on DSA, while ultrasound depicted 89 of 103 arteries. Of the 45 patients in this study, 17 were enrolled in another study whose findings were published in De Cobelli et al (1997).

De Haan et al (1996) prospectively studied 89 renal arteries in 38 patients with therapy-resistant hypertension. Three types of unenhanced MRAs were evaluated in each patient: (1) studies with no cardiac gating; (2) studies with systolic gating, and (3) studies with diastolic gating.[1] All patients underwent contrast angiography as the reference standard. Each image modality was reviewed by two radiologists in a masked fashion. The sensitivity for all three types of MRA was 100%. Specificity was 96% with no gating, 82% with systolic gating, and 96% with diastolic gating.

Fain et al (2001) prospectively studied more than 180 patients with suspected RAS. The authors reported that each patient underwent both small field of view (FOV) 3D CE-MRA and large-FOV 3D CE-MRA[2]. Out of the initial 180 patients, 25 subsequently underwent DSA to study 55 arteries. The authors provided no explanation as to why only 25 out of 180 patients were included in the reported results. The main comparison in this study was between DSA and small-FOV studies. Additionally, DSA was compared with large-FOV studies in 23 of 25 patients. Of the two patients who did not receive large-FOV, one procedure was technically not successful (the reason for the other patient not receiving large-FOV was not explained). Two masked MR angiographers assessed the results of the large-FOV studies, but there was no mention of whether they knew the results of the prior small-FOV studies. The angiographers reached consensus for each observation. When compared to DSA, small-FOV 3D CE-MRA was 97% sensitive and 92% specific.

Hahn et al (1999) prospectively studied 22 patients who had at least one RAS previously confirmed by contrast angiography. Patients received three different MR studies: (1) 3D unenhanced phase-contrast; (2) 3D enhanced phase-contrast, and (3) 3D breath-hold CE-MRA[3]. Two independent radiologists who had no knowledge of the CA results assessed MRAs. Radiologists in consensus graded results of CA and MRA. Sensitivities for each of the 3 MRA studies were 95%, 85%, and 91% respectively while specificities were 38%, 52%, and 79%. For totally occluded vessels, the sensitivity and specificity was 100% for all the MRA techniques.

Huber et al (2001) prospectively studied 41 post-kidney transplant patients and compared DSA to 3D CE-MRA for evaluating postoperative allograft failure or hypertension. After first undergoing DSA, all patients underwent 3D CE-MRA. DSAs were assessed in consensus by two vascular radiologists who were masked to the MRA results. Two MR angiographers, each of whom was masked to DSA results, assessed the MRAs separately, and then together. When compared to DSA, 3D CE-MRA was 100% sensitive for both MR angiographers. Specificity was 97% for Radiologist #1 and 93% for Radiologist #2.

Korst et al (2000) prospectively studied 93 renal arteries in 38 patients with suspected RAS. Two radiologists, unaware of the results of either study, assessed DSA & MRA images. When compared with DSA, the sensitivity and specificity of CE-MRA was 100% and 85% respectively. For totally occluded vessels, sensitivity and specificity were separately reported at 100%. CE-MRA detected 100% of main renal arteries and 76% of accessory arteries.

Mittal et al (2001) prospectively studied 52 arteries in 41 patients (16 were potential kidney donors and 26 had clinical suspicion of RAS). MRA was performed prior to DSA in all but 1 patient. CE-MRA was performed and evaluated by a second radiologist who was masked to the DSA results. CE-MRA identified all 52 main arteries and 7 accessory arteries seen on DSA in patients with suspected RAS. In the potential kidney donors, CE-MRA failed to identify an early branch in one artery and classified it as a main renal artery. In all other instances, CE-MRA correctly identified all vessels seen on DSA. When compared with DSA, CE-MRA was 95% sensitive and 93% specific.

Qanadli et al (2001) prospectively studied 52 renal arteries in 41 patients with suspected RAS using four imaging techniques: captopril Doppler, captopril scintigraphy[4], DSA, and CE-MRA. Initially, 107 patients were enrolled. Of those 107, 30 were excluded for various reasons and an additional 36 patients refused to undergo all 4 examinations. The remaining 41 patients received all four imaging studies within 3 months of each other. The authors separately reported stenosis at the 50% and 70% thresholds. Two radiologists, masked to the results of other exams, read the MRAs. When compared with DSA at >50% stenosis, MRA was 95% sensitive and 82% specific. CE-MRA tended to overestimate stenosis when compared with DSA. At the 50% stenotic threshold, inter-rater reliability was 0.73 for DSA and 0.83 for MRA.

Thorton et al (1999) prospectively studied 62 consecutive patients with suspected secondary hypertension. Each patient underwent DSA followed by CE-MRA within one month. Three masked observers, in consensus, reviewed these studies. CE-MRA identified 129 of the 138 arteries seen on DSA, missing nine accessory arteries. There were two false positive stenoses noted on CE-MRA as well as three false negatives. The sensitivity and specificity for CE-MRA were 88% and 98%, respectively.

Voiculescu et al (2001) prospectively studied 77 renal arteries in 36 consecutive patients, each with suspected RAS. Using 60% as the threshold for hemodynamically significant stenosis, the authors separately reported results for all renal arteries and for main renal arteries only. Two radiologists interpreted the DSAs in a masked and independent fashion. Where the radiologists disagreed on percent stenosis, a mean value was determined. Two other radiologists, masked to the others' results and to the DSA results, interpreted the MRAs. The authors did not discuss how any disagreement in the readings of the MRAs was managed. When compared with DSA for all renal arteries, sensitivity was 89% and specificity was 88%. Although CE-MRA detected 90.9% of all renal arteries, it only detected 55.5% of accessory arteries. Additionally, the authors reported that CE-MRA tended to overestimate the degree of stenosis.

Völk et al (2000) prospectively studied 40 consecutive patients with clinical suspicion of RAS. Four radiologists, masked to all other study results, independently interpreted the MRAs and DSAs. When compared with DSA, the average CE-MRA sensitivity for main renal arteries for all four radiologists was 93%. The average specificity for main renal arteries was 83%. Sensitivity and specificity data for CE-MRA images of accessory renal arteries was not reported. Inter-rater reliability was 0.64 for DSA and 0.49 for CE-MRA.

B. MRA imaging of pelvic (e.g., aortoiliac) arteries not associated with AAA or aortic dissection

CMS reviewed six articles that investigated the use of CE-MRA in the evaluation of pelvic arteries not associated with either AAA or aortic dissection: Dorenbeck et al (2002), Haney et al (1997), Meaney et al (1999), Ruehm et al (2000), Schoenberg et al (2002), and Torreggiani et al (2002). These articles are summarized below.

Dorenbeck et al (2002) studied 15 patients who were to undergo either surgery or endovascular therapy for pelvic and lower extremity occlusive disease. DSA was performed on each patient within three days following bypass surgery, and CE-MRA was subsequently performed within five days of DSA. Four radiologists reviewed the CE-MRAs in an independent and masked fashion. The manner by which the DSAs were reviewed was not stated. The sensitivity and specificity of CE-MRA to detect stenoses of >50% was 100%. CE-MRA did overestimate stenoses in five cases, but each overestimation was by only one grade and this did not affect the lesion's clinical significance.

Haney et al (1997) studied 39 patients with symptomatic peripheral vascular disease. In this prospective, masked analysis, all patients underwent both MRA and CA to evaluate a total of 323 arterial segments within the aortoiliac tree. Arterial segments were divided into four categories: renal, common iliac, external iliac, and internal iliac. A radiologist who was masked to MRA results read catheter angiograms. A separate radiologist masked to the CA results read the CE-MRA images. When compared with CA, CE-MRA sensitivity for detecting >50% stenosis was as follows: 93% renal, 96% common iliac, 93% external iliac, and 96% internal iliac. When compared with CA, CE-MRA specificity for detecting >50% stenosis was as follows: 98% renal, 100% common iliac, 93% external iliac, and 94% internal iliac. The authors did not report interobserver reliability.

Meaney et al (1999) compared the findings on DSA with CE-MRA in imaging the distal aorta, iliac arteries, and lower extremity arteries in patients with arterio-occlusive disease. Twenty consecutive patients who underwent DSA for lower limb claudication also had CE-MRA. Two radiologists, independently and in a masked fashion, reviewed the CE-MRAs. Stenosis was graded as either <50%, >50% or 100% (i.e., occluded).

The authors presented their data for all arterial segments analyzed; there was no breakdown by specific segment. As such, it was not possible to determine the sensitivity/specificity for aorto-iliac segments separate from lower extremity segments. Overall, the sensitivity and specificity of CE-MRA in diagnosing <50% and >50% stenosis was 81% and 89%, respectively. The sensitivity and specificity of MRA in detecting total occlusion was 94% and 97%. The interobserver agreement between the two radiologists who read the MRAs was calculated and demonstrated using kappa statistics. The agreement between the two radiologists in detecting hemodynamically significant stenosis (i.e., >50%) was associated with a kappa of 0.86. The agreement between the two radiologists in detecting complete occlusion (i.e., 100% arterial blockage) was associated with an even greater kappa of 0.93.

Ruehm et al (2000) investigated the ability of CE-MRA to characterize the arterial vasculature from the aortic bifurcation to the lower extremity run-off vessels. They studied 61 consecutive patients referred for contrast angiography for the assessment of peripheral vascular disease (n=50) or graft patency (n= 11). For the purposes of this decision memorandum, only the data on vessels from the aorta to the iliac arteries were considered. Levels of stenosis in these patients were dividedinto five grades: grade 0= normal vessel lumen; grade 1 = <10% stenosis; grade 2 = <50% stenosis; grade 3 = >50% stenosis; and grade 4 =100% occluded. Separate radiologists, masked to the other image results, read the CA and CE-MRA image.

For grade 3 and 4 stenosis, levels that are generally considered to be clinically significant, the overall sensitivity and specificity of CE-MRA was 92% and 99% respectively. Inter-modality concordance between CA and CE-MRA for the detection of grade 3 and 4 stenosis was indicated by a kappa statistic of 0.85. In nine aortic segments there were aneurysmal changes noted on CA, and all nine of these aneurysms were also identified on CE-MRA.

Schoenberg et al (2002) prospectively studied 165 arteries in 41 patients with pelvic and abdominal arterial disease. The authors analyzed renal, common iliac, and internal iliac segments. Three vascular radiologists independently interpreted CE-MRAs and DSAs, and each was masked to the results of the other studies. The CE-MRA mean inter-rater reliability was 0.77 for renal arteries, 0.77 for common iliac arteries, and 0.49 for external iliac arteries.

Torreggiani et al (2002) evaluated the usefulness of CE-MRA as an alternative to either translumbar or brachial catheter angiography in patients with suspected aorto-iliac occlusions. Over an 18-month period all patients with signs and symptoms of aorto-iliac occlusion who presented to their department were recruited for the study. Exclusion criteria included either the ability to successfully undergo perfemoral angiography or a general contraindication to MRI. This resulted in 19 patients being included in the study. Fourteen patients had brachial angiography and 5 had translumbar angiography.

Two radiologists, who were unaware of the angiography results, independently reviewed the CE-MRA images. If the reviewers' readings were not the same, then the two reviewers in consensus arrived at the final MRA reading. The segments analyzed were the lower abdominal aorta, common iliac and external iliac. Occlusions were diagnosed if there was complete signal loss in the affected luminal area with patent lumens seen at either end. CE-MRA had a sensitivity and specificity in diagnosing aortic occlusions of 88% and 100%, respectively. In diagnosing iliac occlusions, the sensitivity and sensitivity of CE-MRA was 100% and 97%, respective

C. Contrast Angiography as an adjunct service to MRA when clinically warranted

As stated earlier, contrast angiography is the “gold standard” for imaging renal and aorto-iliac arteries and is the reference standard against which MRA is being compared in this decision memorandum. As described above, the literature demonstrates that MRA compares favorably to CA. For imaging the renal arteries the literature demonstrates sensitivities ranging from 88% (Thornton 1999) to 100% (Bongers 2000, Chan 2001, DeCobelli 2000, De Haan 1996, Huber 2001, Korst 2000) and specificities ranging from 82% (Qanadli 2001) to 100% (Chan 2001). Imaging the aortoiliac vessels is associated with sensitivities ranging from 81% (Meaney 1999) to 100% (Dorenbeck 2002) and specificities of 89% (Meaney 1999) to 100% (Dorenbeck 2002). However, in rare cases, MRA may not adequately image a renal or aortoiliac artery a it is not a perfect match. In such instances, physicians may also need to obtain a CA. However, given that the two tests are generally very close in agreement (as evidenced by the reviewed studies), CMS expects that it will be the exception rather than the rule when a patient must undergo both MRA and CA to image the same vessel for the same diagnostic work-up.

Summary of Technology Assessments Reviewed

The April 1997 National Blue Cross and Blue Shield TEC assessment entitled “Magnetic Resonance Angiography of the Abdomen” reviewed MRA for use in four anatomic regions: renal arteries, abdominal aorta and mesenteric arteries, portal venous system and hepatic veins, and the systemic venous system. Since this decision memorandum only concerns MRA imaging of renal and aorto-iliac arteries outside of AAA or aortic dissection, only the TEC’s relevant conclusions are reviewed here.

For assessment of the renal arteries, the TEC assessment concluded that MRA for the initial diagnosis of hemodynamically significant (>50%) RAS is a sensitive and specific diagnostic test that is especially beneficial for patients with poor renal function or bilateral RAS. It should be noted that the majority of articles reviewed in this assessment were for unenhanced MRA, reflecting practice standards at the time. The TEC assessment did not comment on the use of MRA in imaging aorto-iliac arteries.

VI. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act. § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the items or services and their expenses must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." § 1862(a)(1)(A).

As previously mentioned in this decision memorandum, MRA of the abdomen and pelvis falls within a Medicare benefit category. In addition, no statutory provision specifically precludes payment. Finally, we have fully examined the medical and scientific evidence submitted with the request for a national coverage determination as well as additional evidence identified by CMS.

A. MRA imaging of renal arteries separate from AAA or aortic dissection

Fourteen studies compared CE-MRA to conventional CA or DSA: (Bongers et al (2000), Chan et al (2001), De Cobelli et al (1996), De Cobelli et al (2000), De Haan et al (1996), Fain et al (2001), Hahn et al (1999), Huber et al (2001), Korst et al (2000), Mittal et al (2001), Qanadli et al (2001), Thorton et al (1999), Voiculescu et al (2001), and Volk et al (2000). When compared with contrast angiography in evaluating hemodynamically significant disease, CE-MRA showed sensitivities ranging from 90% to 100% and specificities from 79% to 100%. In distal renal arteries, CE-MRA was not as sensitive or as specific as CA. Overall, the methodology of these 14 studies was strong with the observers masked and an accepted reference comparison used. In addition, MRA is a non-invasive test that avoids risk of vascular injury that can occur with CA, as well as renal complications that can arise with ionic contrast agents. Therefore, the evidence as a whole is adequate to conclude that MRA is clinically effective, and, thus, reasonable and necessary to image renal arteries separate from AAA or aortic dissection.

B. MRA imaging of aortoiliac arteries separate from AAA or aortic dissection

Six prospective studies compared CE-MRA to CA (Dorenbeck et al 2002, Schoenberg et al 2002, Torreggiani et al 2002, Ruehm et al 2000, Meaney et al 1999, and Haney et al 1997). When compared with CA, CE-MRA sensitivity in the six studies ranged from 81% to 100% and specificity ranged from 89% to 100%. The methodology of these studies was strong with the observers masked and an accepted reference standard used. Given this, CMS believes that the evidence as a whole is adequate to conclude that MRA is reasonable and necessary to image aortoiliac arteries separate from AAA or aortic dissection.

C. Contrast Angiography as an adjunct service to MRA when clinically warranted

Although the literature demonstrates that MRA is reasonable and necessary as a first-line imaging modality for renal and aortoiliac arteries separate from aortic abdominal aneurysms and aortic dissections, this technique's sensitivity and specificity vis-à-vis contrast angiography is not 100%. CMS recognizes that in certain clinical situations, information obtained through MRA may not be adequate to address the patient's clinical condition. In such cases, physicians may need to perform contrast angiography in addition to MRA in order to obtain the needed clinical information. Although performing MRA and CA in the same patient for the same diagnostic evaluation should not be performed routinely, there may be rare clinical situations that warrant such multiple imaging studies, because MRA did not adequately image a renal or aortoiliac vessel that the study was intended to evaluate. If physicians are able to demonstrate medical necessity, they should be allowed to perform CA following MRA in those rare cases.

D. General Considerations

MRA, as with contrast angiography, is not part of an initial office visit. Standard medical care is to order an MRA only if physician history, physical examination and standard assessment tools provide insufficient information for patient management, and obtaining an MRA has a high probability of positively affecting patient management. Ordering an MRA in other circumstances would not be reasonable and necessary. It is also customary to have available contemporaneous medical documentation supporting the physician's decision to obtain an MRA or to obtain a CA following an MRA.

Because MRA is relatively safe, as compared to CA, CMS is concerned that expanding coverage could lead to the inappropriate ordering of MRA studies when a proper initial evaluation had not been performed or when the probability that the MRA would positively affect patient management is low. Therefore, CMS believes the local contractors should take steps to monitor possible inappropriate use and over-utilization of MRA. MRA should only be ordered if a standard assessment does not provide sufficient information for patient management and obtaining an MRA has a high probability of positively affecting patient management, such as when clinical findings or other tests suggest a strong likelihood of finding a surgically correctable vascular stenosis. An adjunct CA should only be ordered if the MRA is inconclusive. Given the similar accuracy between MRA and CA, the number of cases in which it would be necessary to order both tests should be exceedingly small. Our contractors should monitor claims closely for patients who receive both tests. If CMS determines that MRA is being used inappropriately or over-utilized, CMS may elect to reconsider its national coverage policy and limit coverage.

In summary, the evidence is adequate to conclude MRA is reasonable and necessary for imaging:

1. Renal arteries separate from abdominal aortic aneurysm (AAA) or aortic dissection, and
2. Aortoiliac arteries separate from abdominal aortic aneurysm (AAA) or aortic dissection.
3. When clinically warranted and supported by medical necessity, contrast angiography may be performed as an adjunct imaging modality to MRA.

DECISION

CMS intends to issue a positive national coverage determination expanding coverage of MRA to include imaging the renal arteries and the aortoiliac arteries in the absence of abdominal aortic aneurysm or aortic dissection. MRA should be obtained in those circumstances in which using MRA is expected to avoid obtaining contrast angiography (CA), when physician history, physical examination and standard assessment tools provide insufficient information for patient management, and obtaining an MRA has a high probability of positively affecting patient management. However, CA may be ordered after obtaining the results of an MRA in those rare instances where medical necessity is demonstrated. Medicare contractors should establish criteria for demonstrating medical necessity.

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1 Respiratory motion, intestinal peristalsis, and arterial pulsation can degrade MRA image quality. The impacts of these motions can be reduced through various techniques. Systolic gating refers to synchronizing image acquisition with the end of ventricular contraction. Diastolic gating refers to synchronizing with the end of ventricular relaxation. Arterial pulsations are at a minimum at these intervals of the cardiac cycle.

2 Field of view refers to the anatomic area that is visible during image acquisition.

3 Having a patient hold their breath during image acquisition can reduce the image quality degradation caused by respiratory motion.

4 Captopril scintigraphy is a non-invasive diagnostic study used to evaluate renal artery blood flow.

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